

REMARKS

The above amendments to the above-captioned application along with the following remarks are being submitted as a full and complete response to the Official Action dated June 24, 2005. In view of the above amendments and the following remarks, the Examiner is respectfully requested to give due reconsideration to this application, to indicate the allowability of the claims, and to pass this case to issue.

Upon entry of the foregoing amendment, claims 3-13 are pending in the application. These changes are believed to introduce no new matter, and their entry is respectfully requested. Support for the claim amendments can be found throughout the specification and claims as originally filed, and specifically on pages 3-6 and figures 1-4. These amendments and the following remarks have adequately addressed all the grounds for rejections and objections or have rendered them moot. Applicants respectfully request the Examiner reconsider all outstanding rejections and that they be withdrawn.

Objection to the Title

The Examiner is of the opinion that the original Title to the Invention: "Hybridization Device with a Sheet or a Bottom Convex for Fixedly Placing a Cover Glass Thereon" is not clearly indicative of the invention to which the claims are directed.

Applicants respectfully disagree and assert that pursuant to 37 C.F.R. § 1.72, the title is required to be "as short and as specific as possible." The old title is "clearly indicative" of the invention and recites at least one major embodiment of the device. Said old title enhances the information value of the title by reciting embodiments that facilitate indexing, classification, and searching etc, and is clearly indicative of the base invention.

It does appear as if the Examiner's objection is based on the Examiner's lexicographic difficulties with the word "device", said difficulties adequately addressed below. However, in order to advance the prosecution of this application, the title of the application has been amended to "Biopolymer Hybridization Chamber." Applicants respectfully ask the Examiner to recognize this title as the new Title of the Invention and additionally would like to inform the Examiner that they would welcome suggestions of more "clearly indicative" titles from the Examiner.

Rejection under 35 U.S.C. §112, 1st paragraph

Claims 3 – 13 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description. According to the Examiner, the previous amendments to claims 3 -11, wherein “device” was replaced by “kit” and wherein the word “kit” was not used in the instant application constitutes new matter. As the Examiner would recall, Applicants used the word “kit” in order to advance the prosecution of this Application pursuant to the Examiner’s suggestion that the device of the instant invention more clearly defines a kit. It was the Applicants’ belief and it still is the Applicants’ belief that no subject matter is disclaimed nor is any new subject matter attained by using the words “kit” and “device” interchangeably. Nevertheless, Applicants have amended the claims to recast them in their original form and would now traverse this ground for rejection under the following paragraphs:

There is no Judicially Explicated Distinction Between “Device” and “Kit” and Applicants Should not be Constrained to recognize U.S.P.T.O’s Colloquial Distinctions between “Device” and “Kit”

In the first Office Action, the Examiner pointed out that if structural connections in fact do not exist between the different parts of the device of the present invention, that Applicants should consider having claims drawn to a “kit,” which can be comprised of various non-connected elements or components. Although, Applicants were concerned about the Examiner’s metaphysical distinctions between a “device” and a “kit”, Applicants, while noting that a disassembled device is no less a device than a device yet to be assembled, nevertheless drew the claims to a kit in order to advance the prosecution of this Application.

In an informal telephonic conversation on September 7, 2005, in which Applicants’ representative tried to attain a common understanding of the meaning of “device” and “kit” in order to advance the prosecution of this Application, the Examiner appeared to be alluding to a colloquial distinction made in the U.S.P.T.O between “device” and “kit” that appears to have been made purely as a matter of administrative and classification convenience, and not based on any generally accepted distinction which the Examiner now foists upon the instant inventors.

Applicants are not aware of any judicially explicated distinction between “Device” and “Kit” and as such, it being merely a matter of lexicographic preferences, Applicants

assert that they should not be bound by it and that the Examiner should duly recognize their lexicographic latitude.

Contrary to the Examiner's view and characterization of the invention, the instant invention provides structural connections between the various parts of the device when in use. The cooperative relationship between the elements of the device is set forth such that gaps do not exist between the necessary structural connections. The claimed device is composed of a tray, a sheet, a case, and a cap. These elements provide for the make-up of the device, which can be used to conduct hybridization reactions.

Applicants do not share the Examiner's distinction between a "device" and a "kit." If the touch stone is "structural connectedness" then by implication, a kit once assembled for its intended purpose becomes a device and a disassembled device becomes a kit.

In terms of plain and ordinary meaning, the English dictionary defines a device as "that which is formed or invented for a specific use." Similarly, a kit is defined as "a set or collection of tools or other objects for a special purpose." *See Webster Dictionary of English Language.* Applicants believe that the instant invention, directed to a device for conducting hybridization reactions is more consistent with the plain and ordinary meaning of "device," than the Examiner's "structural connectedness" test. A hybridization device would necessarily contain at least two separate components—the probe container and the sample container—to be contacted for hybridization test.

In terms of empirical evidence, there is also no suggestion of the distinction which the Examiner imposes upon the Applicants. Between 1976 to the present, 273,915 issued Patents have the word, "device" in their title and only 4,082 have the word "kit" in their title. It does suggest at least that "device" is being used as a generic word for "kit" A further search through most of those patents referring to a device shows that in most cases, they have multi-component embodiments while not in use. Similarly, there are about 10 patents having the words, "device" and "hybridization" in their title and about 7 patents having the words, "kit" and "hybridization" in their title. An even further search showed that the "devices" comprised multi-components that are not structurally connected when not in use. If the empirical evidence itself is controlling, then a device may be thought of as an apparatus having structurally connected parts when in use. In that case, because the parts of the device of the present invention are structurally connected when in use, this invention is quite clearly describable as a device.

Figure 4 of the present invention shows a perspective view of the “united hybridization device.” That phrase, “united hybridization device” is very much consistent with the generally understood notion that an assembled kit is a device. Whereas the Examiner sees the cap, the cases, the films, and the tray, as separate and distinct tools more appropriately comprising a kit, Applicants have elected to describe them as embodiments of the instant device for conducting hybridization and related tests. In particular, a hybridization kit would necessarily encompass not only the device of this invention, but also the droppers, probe readers, probe labels, reagents, sample preparation kit and so on necessary to carry out hybridization reactions. Therefore to describe the current invention as directed to a hybridization kit when the other materials mentioned above necessary to carry out a hybridization reaction are not part of the present invention would not be technically accurate. Applicants quite simply and elegantly invented a hybridization chamber and one of skill in the art knows to bring along other accessories in order to carry out the hybridization assays.

Even then, rarely are the so-called devices ever used by themselves. For instance, at what point does the detachable cap of a water bottle convert the bottle from a water-containing device to a water-containing kit? Is the Examiner contending while the cap is separated from the bottle, that the arrangement be called a water-containing kit and that while the cap is connected to the bottle, it should be called a water-containing device? Applicants believe that the “structural connectedness” test for the Examiner’s notion of a device applies only when the device is in use for the specific purpose for which it was made. In that sense, the Examiner must recognize that there is no bright line distinction between a “device” and a “kit”, a device being in effect an assembled kit. In particular, where as here, the Examiner’s structural connectedness test is met upon uniting the embodiments of the present invention, the written description is not fatally flawed by referring generally and colloquially to the instant invention as a device instead of a kit.

THE EXAMINER IS CONSTRAINED TO RECOGNIZE THE MANNER IN WHICH THE WORD “DEVICE” IS USED IN THE SPECIFICATION

The foregoing is presented as if incorporated herein in its entirety.

Where words in a patent claim have no specialized meaning to persons of skill in the art, the ordinary meaning of those words to those skilled in the art control the construction of the words, unless the evidence indicates that the inventor used them differently. Karlin Technology, Inc. v. Surgical Dynamics, Inc., 177 F.3d 968 (Fed. Cir. 1999).

It is well settled that claim terms should be construed along the lines of their plain and ordinary meaning in light of the specification. Further, being their own lexicographers, if the specification warrants a departure from the plain and ordinary meaning of a term, then such departure is required for proper construction of the claims.

On page 3, paragraph 7, Applicants wrote that “Figures 1A and 1B are perspective and cross-sectional views showing a structure of a **hybridization device** according to Embodiment 1 of the present invention respectively.”

On page 4, paragraph 9, Applicants wrote that “Figures 2A and 2B are perspective and cross-sectional views showing a structure of a **hybridization device** according to Embodiment 2 of the present invention respectively.”

By virtue of the above citations from the Specification, Applicants quite clearly and distinctly indicated how they wish the phrase, “hybridization device” to be construed – namely according to the embodiments of Figures 1A, 1B, 2A, and 2B and their equivalents.

Whatever may be the Examiner’s notion of the plain and ordinary meaning of the word, “device” and however repugnant the Examiner may find the meaning which Applicants have expressly indicated that they wish to accord said word, Applicants’ clearly defined sense of the word “device” controls as a matter of law. Applicants therefore, respectfully ask the Examiner to withdraw this ground for rejection.

THERE IS NO LEGAL REQUIREMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, THAT APPLICANTS SPECIFICALLY LIST EVERY SPECIES AND GENOTYPIC PROFILE OF BIOPOLYMERS THAT CAN BE HYBRIDIZED USING THEIR HYBRIDIZATION UTILITY DEVICE

The Examiner asserts that claims 12 and 13 fairly encompass any manner and all manners of biopolymers. The Examiner further asserts that there is no adequate description of the biopolymers that are required to be present on the slide glass. Further, the Examiner points out that there is no Sequence Listing for any protein or nucleic acid that has been filed. Applicants vigorously and categorically disagree with this ground for rejection and hereby traverse as follows.

The term “hybridization” has a clear, definite and unmistakable connotation in the Biochemical arts and applies to biopolymers. In its broadest sense, hybridization refers to the act or process of forming a macromolecular hybrid. One of skill in the art knows that not all

biopolymers are hybridizable and indeed, the idea of conducting hybridization assays is to ascertain the degree of hybridizability of a probe sequence or molecule with a complimentary sequence or macromolecule to the extent that it exists in a given sample. Hybridization itself being the test of ascertaining the degree of affinity between macromolecules or macromolecules and their ligands, based on complementarity or such other biochemical affinity between the probe sequences and the macromolecular sequence beings assayed for. The device of the present invention is quite simply an inventive chamber having the utility of a hybridization chamber. The device of the instant invention therefore applies to, and can be used, as the artisan desires for all sorts of hybridizable biopolymer assays and the requirement by the Examiner to specifically describe all of them, even up to the minutiae of their genotypic profile, clearly, if not unreasonably, exceeds the bounds of the law. Furthermore, the Biochemical literature is replete with techniques for immobilizing probes or biopolymers on glass surfaces and a given artisan is free to choose whatever method suits their research and it is clearly not the object of the present invention to circumscribe what uses and for what polymers this invention might be used.

By analogy, is the inventor of a test tube for carrying out reactions required to specifically enumerate all manner of chemicals that can be reacted therein or the inventor of a Petri -dish for culturing microorganisms required to enumerate all microbes that may be cultured therein? To that extent, Applicants respectfully ask the Examiner to recognize this invention as a utility chamber for carrying out hybridization assays and to not unduly broaden or attempt to unduly narrow the invention by specifying that the infinite permutations of biopolymers that can be subjected to hybridization assays be specifically enumerated or for that matter, that the infinite permutations of experimental conditions under which a given researcher may wish to use this utility device be specifically enumerated.

On the basis of the foregoing, Applicants respectfully ask the Examiner to withdraw his rejections to claims 12 and 13 and to send the Application to issue.

Conclusion

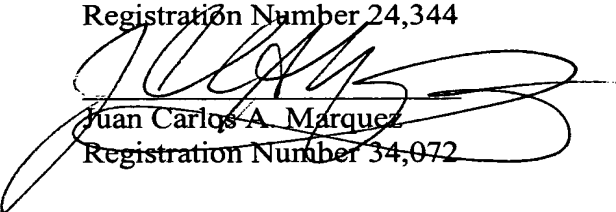
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes,

for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Response is respectfully requested.

Respectfully submitted,

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September 14, 2005

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